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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,556	08/09/2001	Stephen A. Yenko	032405-058	5402
33109	7590	03/23/2004		
CARDICA, INC. 900 SAGINAW DRIVE REDWOOD CITY, CA 94063			EXAMINER BAXTER, JESSICA R	
			ART UNIT 3731	PAPER NUMBER 9

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/924,556

Applicant(s)

YENCHO ET AL.

Examiner

Jessica R Baxter

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-84 is/are pending in the application.
- 4a) Of the above claim(s) 30-36 and 59-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-58 and 77-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Art Unit: 3731

DETAILED ACTION

Election/Restrictions

1. Claims 30-36 and 59-76 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 8.

2. The requirement is still deemed proper and is therefore made FINAL.

Specification

3. The specification was objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction is noted and the objection is withdrawn.

Double Patenting

4. Claims 77-84 were provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 60-67 of copending Application No. 09/886074. Correction is noted and the rejection is withdrawn.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 3731

6. Claims 37-43, 55-58 and 77-84 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-42 and 56-59 of copending Application No. 09/886074. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim an anastomosis tool comprising first and second tubes, wherein one of the tubes has a side hole (claims 37-43), an anastomosis tool including a vessel penetrating member (claims 55-58).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

7. Claims 47, 48, 52 and 53 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Correction is noted and the rejection is withdrawn.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 37 and 41-49 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,024,748 to Manzo et al.

Art Unit: 3731

Regarding claims 37 and 45, Manzo discloses an anastomosis device applicator comprising a first tube configured to receive an anastomosis device (FIG. 19 unit 16); a second tube concentric with the first tube (tube 46), the first and second tubes configured for movement with respect to one another (FIG. 19 and 20); and a side hole in at least one of the first and second tubes configured to allow the graft vessel to pass out the side of the tube (FIG. 19 IMA), wherein the applicator has a pre-deployment configuration where at least one tube extends beyond the distal end of the device (FIG. 19).

Regarding claim 41, Manzo discloses that the first tube is configured for removable connection to the anastomosis device (Column 8 lines 45-57).

Regarding claim 42, Manzo discloses that the anastomosis applicator further comprises a handle connected to the first and second tubes with a mechanism for deploying the anastomosis device (handle 12).

Regarding claims 43, Manzo discloses that the first tube includes a plurality of connecting members at a distal end and the anastomosis device includes a plurality of features arranged to removably connect to the plurality of connecting members (FIG. 7 indentations for curves of the clips).

Regarding claims 44 and 49, Manzo discloses an anastomosis device configured for connecting a graft vessel to a target vessel (FIG. 39).

10. Claims 37, 38, 39, 40 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,833,698 to Hinchliffe et al.

Regarding claims 37 and 38, Hinchliffe discloses an anastomosis device applicator comprising a first tube configured to receive an anastomosis device; a second tube concentric with the first tube, the first and second tubes configured for movement with

Art Unit: 3731

respect to one another; and a side hole in at least one of the first and second tubes configured to allow the graft vessel to pass out the side of the tube (FIG. 12).

11. Claims 55-58 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,976,178 to Goldsteen et al.

Regarding claims 55, 56 and 57, Goldsteen discloses an anastomosis applicator comprising a first tube (440) configured for receiving a one-piece anastomosis device, a second tube (410) concentric with the first tube, the first and second tubes configured for movement with respect to one another and configured for deployment of the anastomosis device; a vessel penetrating member (412) configured for incision of the target vessel; and wherein the applicator is configured to maintain contact with the target vessel from the time of incision through complete deployment of the anastomosis device (FIGS. 18-22b).

Regarding claims 58, Goldsteen discloses that the vessel penetrating member is configured for positioning inside the concentric tubes (FIG. 15).

12. Claims 50, 51, 52, 53, 54, 77, 78, 80 and 81 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,695,504 to Gifford, III et al.

Regarding claims 50, Gifford discloses an anastomosis applicator comprising a first tube (124) configured for receiving an anastomosis device, a second tube (125) concentric with the first tube, the first and second tubes configured for movement with respect to one another and configured for deployment of the anastomosis device (FIG. 5a-5f); a vessel penetrating member configured for incision of the target vessel (136); and wherein the applicator is configured to maintain contact with the target vessel from the time of incision through complete deployment of the anastomosis device (FIG. 5b-5e).

Regarding claim 51, Gifford discloses that the second tube is rotatable with respect to the first tube (Column 18 lines 13-20).

Regarding claims 54 and 81, Gifford discloses that the anastomosis device is configured for connecting a graft vessel to a target vessel (FIG. 5g).

Regarding claim 77, Gifford discloses a method comprising : receiving a one-piece anastomosis device on an anastomosis device applicator having a vessel penetrating member (136); connecting a graft vessel to the anastomosis device on the anastomosis device applicator; penetrating a target vessel with the vessel penetrating member of the anastomosis device applicator; advancing the anastomosis device into the penetration in the target vessel; and deploying the anastomosis device with the anastomosis device applicator (FIG. 5b-5g).

Regarding claim 78, Goldsteen discloses that the step of deploying the anastomosis device is performed by moving two tubes of the anastomosis device applicator with respect to one another (FIG. 5b-5g).

Regarding claim 80, Goldsteen discloses that the vessel penetrating member is configured for positioning inside the concentric tubes (FIG. 4).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 79 and 82-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gifford III et al. '504.

Gifford discloses the claimed invention except for the anastomosis device being a one-piece anastomosis device (FIG 1). Gifford teaches alternate anastomosis devices that include using a one-piece anastomosis device (FIGS. 27-28). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Gifford with a one-piece anastomosis device since Gifford teaches many different anastomosis devices that may be used to attach a graft vessel to a target blood vessel.

Response to Arguments

15. Applicant's arguments filed December 31, 2003 have been fully considered but they are not persuasive.

16. The double patenting rejection is maintained since both applications contain claims drawn to an anastomosis tool. The amendments to the anastomosis device does not affect the claimed subject matter of the claim since it is drawn to an anastomosis tool to be used with an anastomosis device. The anastomosis tool may be used with either of the anastomosis devices. Therefore, they are not patentably distinct.

17. Applicant argues that Manzo does not disclose an anastomosis device that is unitary. However, the claimed subject matter is drawn to an anastomosis tool, the anastomosis device is not positively recited. The question is whether Manzo's device could be used with an anastomosis device that is unitary. It is believed that Manzo could be used with such an anastomosis device and the rejection is deemed proper.

18. Applicant argues that Hinchcliffe does not disclose an anastomosis device that has two spaced apart flanges. However, the claimed subject matter is drawn to an anastomosis tool, the anastomosis device is not positively recited. The question is whether Hinchcliffe's device could be

Art Unit: 3731

used with an anastomosis device that has two spaced apart flanges. It is believed that Hinchcliffe could be used with such an anastomosis device and the rejection is deemed proper.

19. Applicant argues that Goldsteen and Gifford do not disclose the tip penetrating the intact tissue of the target vessel. However from, Column 13 lines 1-9, it is clear that Goldsteen does penetrate the target blood vessel. The fact that the target blood vessel is intact is irrelevant since that limitation is not claimed.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica R Baxter
Examiner
Art Unit 3731


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